IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

)
REX MEDICAL, L.P.)
)
Plaintiff,)
)
v.) C.A. No. 05-28-GMS
DATASCOPE CORPORATION,) JURY TRIAL DEMANDED
Defendant.)
)

DEFENDANT DATASCOPE CORP.'S ANSWER AND COUNTERCLAIMS

Defendant Datascope Corp. ("Datascope"), for its response to the complaint of plaintiff Rex Medical LP ("Rex"), alleges as follows and demands a trial by jury on all issues so triable:

- Denies the allegations of paragraph 1 of the complaint, except 1. admits that Rex purports to seek the relief described, and that Rex has transferred certain items of technology to Datascope.
- Denies knowledge or information sufficient to form a belief as to 2. the truth of the allegations of paragraph 2 of the complaint.
- Admits the allegations of paragraph 3 of the complaint, except 3. Datascope states that the correct street address for Datascope is 14 Philips Parkway.
- The allegations of paragraph 4 are legal conclusions as to which no 4. responsive pleading is required, and therefore those allegations are denied.

063982.1001 WP3:1095351.1

- 5. The allegations of paragraph 5 are legal conclusions as to which no responsive pleading is required, and therefore those allegations are denied, except Datascope admits that the contracts between the parties contain forum selection clauses requiring disputes to be resolved in courts sitting in Delaware.
- 6. The allegations of paragraph 6 are legal conclusions as to which no responsive pleading is required, and therefore those allegations are denied, except Datascope admits that Rex purports to seek the relief requested.
- 7. Denies knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 7 of the complaint, except Datascope admits that Rex holds itself out as a company capable of designing, developing and bringing to market medical devices.
- 8. Denies the allegations of paragraph 8 of the complaint, except Datascope admits that it is engaged in the business, among others, of developing, manufacturing and marketing products for the clinical health care market.
- 9. Denies the allegations of paragraph 9 of the complaint, except Datascope admits that prior to May 14, 2003, Rex had purported to develop certain knowledge, intellectual property, patents and patent applications, know-how and experience related to a thrombectomy product now known as "ProLumen," and that Rex purported to be developing an enhanced thrombectomy product now referred to by the parties as "ProLumen Plus."
- 10. Admits that ProLumen is a self-contained, disposable, hand held thrombectomy device designed for thrombus maceration and removal in dialysis access grafts, but denies knowledge or information sufficient to form a belief as to the truth of

- 2 - WP3:1095351.1 063982.1001

the allegations in paragraph 10 of the complaint about the final product characteristics of ProLumen Plus.

- 11. Admits that Rex and Datascope entered into a Technology

 Transfer Agreement dated May 14, 2003 ("Thrombectomy Transfer Agreement"); to the extent that the remaining allegations of paragraph 11 of the complaint are characterizations or interpretations of the Thrombectomy Transfer Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- 12. In response to paragraph 12 of the complaint, Datascope admits that a true and correct copy of the Thrombectomy Transfer Agreement is attached as Exhibit A to the complaint; to the extent that the remaining allegations of paragraph 12 of the complaint are characterizations or interpretations of the Thrombectomy Transfer Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- 13. To the extent that the allegations of paragraph 13 of the complaint are characterizations or interpretations of the Thrombectomy Transfer Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- 14. To the extent that the allegations of paragraph 14 of the complaint are characterizations or interpretations of the Thrombectomy Transfer Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.

- 3 -WP3:1095351.1

- 15. To the extent that the allegations of paragraph 15 of the complaint are characterizations or interpretations of the Thrombectomy Transfer Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- 16. To the extent that the allegations of paragraph 16 of the complaint are characterizations or interpretations of the Thrombectomy Transfer Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- 17. To the extent that the allegations of paragraph 17 of the complaint are characterizations or interpretations of the Thrombectomy Transfer Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- 18. To the extent that the allegations of paragraph 18 of the complaint are characterizations or interpretations of the Thrombectomy Transfer Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- 19. To the extent that the allegations of paragraph 19 of the complaint are characterizations or interpretations of the Thrombectomy Transfer Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- 20. To the extent that the allegations of paragraph 20 of the complaint are characterizations or interpretations of the Thrombectomy Transfer Agreement, they

- 4 - WP3:1095351.1 063982.1001

are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.

- 21. To the extent that the allegations of paragraph 21 of the complaint are characterizations or interpretations of the Thrombectomy Transfer Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- 22. To the extent that the allegations of paragraph 22 of the complaint are characterizations or interpretations of the Thrombectomy Transfer Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
 - 23. Denies the allegations of paragraph 23 of the complaint.
- 24. Denies the allegations of paragraph 24 of the complaint, except admits that some variations from the schedules and deadlines set forth in the Thrombectomy Transfer Agreement occurred.
 - 25. Denies the allegations of paragraph 25 of the complaint.
- 26. Denies the allegations of paragraph 26 of the complaint, except admits (i) that Rex and Datascope interacted at various times concerning the Thrombectomy Transfer Agreement, (ii) that Datascope properly discharged its duties under the Thrombectomy Transfer Agreement, and (iii) that Datascope brought ProLumen to the market in or around March 2004.
- 27. Denies the allegations of paragraph 27 of the complaint, except admits that (i) Rex filed and obtained FDA 510(k) approval for ProLumen, (ii) Rex

- 5 - WP3:1095351.1 063982.1001

completed clinical testing of ProLumen in or around February 2004, and (iii) Datascope began offering ProLumen for sale in or around March 2004.

- 28. For its response to paragraph 28 of the complaint, Datascope admits that, as of April 1, 2004, it had paid at least \$5,000,000 to Rex; and states that, to the extent paragraph 28 purports to characterize the Thrombectomy Transfer Agreement, Datascope respectfully refers the Court to such agreement for a complete and accurate description of its terms.
- 29. Denies the allegations of paragraph 29 of the complaint, except admits that Rex has failed to meet the deadlines set forth in the Thrombectomy Transfer Agreement with respect to the Future Transferred Product (i.e., ProLumen Plus), or otherwise to deliver ProLumen Plus to Datascope.
- 30. Denies the allegations of paragraph 30 of the complaint, except denies knowledge or information sufficient to form a belief as to the truth of the allegations that the acts and/or omissions of Clinical Instruments, a third party vendor selected by Rex, delayed compliance with the schedules and deadlines in the Thrombectomy Transfer Agreement.
 - 31. Denies the allegations of paragraph 31 of the complaint.
- 32. Denies the allegations of paragraph 32 of the complaint, except denies knowledge or information sufficient to form a belief as to the truth of the allegations concerning Rex's "substantial resources and financial support."
- 33. Denies the allegations of paragraph 33 of the complaint, except admits that in the period following July 1, 2004, Datascope informed Rex, in sum or

- 6 -WP3:1095351.1 substance, that, in accordance with the Thrombectomy Transfer Agreement, Datascope was no longer obligated to pay \$2,500,000 to Rex for delivery of ProLumen Plus.

Case 1:05-cv-00028-GMS

- 34. Denies the allegations of paragraph 34 of the complaint, except admits that Datascope has not made the payment of \$2,500,000 described in paragraph 3A(v) of the Thrombectomy Transfer Agreement.
- 35. Admits the allegations of paragraph 35 of the complaint, and states that, after July 1, 2004, Datascope was not obligated to pay Rex \$2,500,000 for the delivery of ProLumen Plus.
- 36. Denies the allegations of paragraph 36 of the complaint, except admits that prior to November 17, 2003, Rex purported to have developed certain knowledge, intellectual property, patents and patent applications, know-how and experience related to short sheath and locking sheath products for use in thrombectomy of synthetic dialysis access grafts.
 - 37. Admits the allegations of paragraph 37 of the complaint.
- November 17, 2003, Rex and Datascope entered into two technology transfer agreements relating to short sheath and locking sheath products, and that true and correct copies of such agreements are attached as exhibits B and C to the complaint (defined below as the "Innermark Transfer Agreement" and the "Innerlock Transfer Agreement"); to the extent that the remaining allegations of paragraph 38 of the complaint are characterizations or interpretations of the Innermark or Innerlock Transfer Agreements they are denied, and Datascope respectfully refers the Court to those agreements for a complete and accurate description of their terms.

- 7 - WP3:1095351.1 063982.1001

- To the extent that the allegations of paragraph 39 of the complaint 39. are characterizations and interpretations of the Technology Transfer Agreement, dated November 17, 2003, relating to a short sheath product ("Innermark Transfer Agreement") they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- To the extent that the allegations of paragraph 40 of the complaint 40. are characterizations and interpretations of the Technology Transfer Agreement dated November 17, 2003, relating to a locking sheath product ("Innerlock Transfer Agreement"), they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- To the extent that the allegations of paragraph 41 of the complaint 41. are characterizations or interpretations of the Innermark and/or Innerlock Transfer Agreements, they are denied, and Datascope respectfully refers the Court to those agreements for a complete and accurate description of their terms.
- To the extent that the allegations of paragraph 42 of the complaint 42. are characterizations or interpretations of the Innermark and/or Innerlock Transfer Agreements, they are denied, and Datascope respectfully refers the Court to those agreements for a complete and accurate description of their terms.
- To the extent that the allegations of paragraph 43 of the complaint 43. are characterizations or interpretations of the Innermark and/or Innerlock Transfer Agreements, they are denied, and Datascope respectfully refers the Court to those agreements for a complete and accurate description of their terms.

-8-063982.1001 WP3:1095351.1

- Case 1:05-cv-00028-GMS Document 7
- To the extent that the allegations of paragraph 44 of the complaint 44. are characterizations or interpretations of the Innermark and/or Innerlock Transfer Agreements, they are denied, and Datascope respectfully refers the Court to those agreements for a complete and accurate description of their terms.
- To the extent that the allegations of paragraph 45 of the complaint 45. are characterizations or interpretations of the Innermark and/or Innerlock Transfer Agreements, they are denied, and Datascope respectfully refers the Court to those agreements for a complete and accurate description of their terms.
- To the extent that the allegations of paragraph 46 of the complaint 46. are characterizations or interpretations of the Innermark and/or Innerlock Transfer Agreements, they are denied, and Datascope respectfully refers the Court to those agreements for a complete and accurate description of their terms.
- To the extent that the allegations of paragraph 47 of the complaint 47. are characterizations or interpretations of the Innermark and/or Innerlock Transfer Agreements, they are denied, and Datascope respectfully refers the Court to those agreements for a complete and accurate description of their terms.
- To the extent that the allegations of paragraph 48 of the complaint 48. are characterizations or interpretations of the Innermark and/or Innerlock Transfer Agreements, they are denied, and Datascope respectfully refers the Court to those agreements for a complete and accurate description of their terms.
 - Denies the allegations of paragraph 49 of the complaint. 49.

-9-063982.1001 WP3:1095351.1

- Denies the allegations of paragraph 50 of the complaint, except 50. admits that Rex has been significantly delayed in, and has failed to effect, the delivery of the Innermark and Innerlock sheaths to Datascope.
- Denies the allegations of paragraph 51 of the complaint, except 51. admits that Datascope recommended that Rex use Cadmold on the Innermark and Innerlock projects.
 - Denies the allegations of paragraph 52 of the complaint. 52.
 - Denies the allegations of paragraph 53 of the complaint. 53.
- Denies the allegations of paragraph 54 of the complaint, except 54. admits that the parties exchanged various communications about the alleged causes of delays or other problems associated with the ProLumen, ProLumen Plus, Innermark and Innerlock projects.
- Denies the allegations of paragraph 55 of the complaint, except 55. admits that Datascope is not responsible for causing significant delays in the development, testing, approval, delivery or marketing of ProLumen, ProLumen Plus, or the Innermark or Innerlock sheaths.
- Denies the allegations of paragraph 56 of the complaint, and states 56. that any settlement discussions between the parties to which paragraph 56 may allude are subject to Rule 408 of the Federal Rules of Evidence.
- Denies the allegations of paragraph 57 of the complaint, except 57. admits that Rex purports to seek the indicated relief.

- 10 -063982.1001 WP3:1095351.1

COUNT I

- 58. For its response to paragraph 58 of the complaint, Datascope incorporates, as if fully set forth herein, its responses to paragraphs 1 through 57 of the complaint.
- To the extent that the allegations of paragraph 59 of the complaint 59. are characterizations or interpretations of the Thrombectomy Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- To the extent that the allegations of paragraph 60 of the complaint 60. are characterizations or interpretations of the Thrombectomy Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- To the extent that the allegations of paragraph 61 of the complaint 61. are characterizations or interpretations of the Thrombectomy Agreement, they are denied, and Datascope respectfully refers the Court to that agreement for a complete and accurate description of its terms.
- The allegations of paragraph 62 are legal conclusions as to which 62. no responsive pleading is required, and therefore those allegations are denied.
 - Denies the allegations of paragraph 63 of the complaint. 63.
 - Denies the allegations of paragraph 64 of the complaint. 64.
 - Denies the allegations of paragraph 65 of the complaint. 65.

COUNT II

- 11 -063982.1001 WP3:1095351.1

- For its response to paragraph 66 of the complaint, Datascope 66. incorporates, as if fully set forth herein, its responses to paragraphs 1 though 65 of the complaint.
- To the extent that the allegations of paragraph 67 of the complaint 67. are characterizations or interpretations of the Innermark and/or Innerlock Transfer Agreements, they are denied, and Datascope respectfully refers the Court to those agreements for a complete and accurate description of their terms.
- To the extent that the allegations of paragraph 68 of the complaint 68. are characterizations or interpretations of the Innermark and/or Innerlock Transfer Agreements, they are denied, and Datascope respectfully refers the Court to those agreements for a complete and accurate description of their terms.
- To the extent that the allegations of paragraph 69 of the complaint 69. are characterizations or interpretations of the Innermark and/or Innerlock Transfer Agreements, they are denied, and Datascope respectfully refers the Court to those agreements for a complete and accurate description of their terms.
- The allegations of paragraph 70 are legal conclusions as to which 70. no responsive pleading is required, and therefore those allegations are denied.
 - Denies the allegations of paragraph 71 of the complaint. 71.
 - Denies the allegations of paragraph 72 of the complaint. 72.
 - Denies the allegations of paragraph 73 of the complaint. 73.

COUNT III

For its response to paragraph 74 of the complaint, Datascope 74. incorporates, as if fully set forth herein, it responses to paragraphs 1 through 73 of the complaint.

- 12 -063982.1001 WP3:1095351.1

- Denies the allegations of paragraph 75 of the complaint, except 75. admits that Rex transferred to Datascope certain of the items required to be transferred under the Thrombectomy Transfer Agreement with respect to ProLumen, but almost none of the items required to be transferred with respect to ProLumen Plus.
- Denies the allegations of paragraph 76 of the complaint, excepts 76. admits that Datascope accepted delivery from Rex of certain of the items required to be transferred under the Thrombectomy Transfer Agreement with respect to ProLumen and ProLumen Plus.
 - Denies the allegations of paragraph 77 of the complaint. 77.
 - Denies the allegations of paragraph 78 of the complaint. 78.

COUNT IV

- For its response to paragraph 79 of the complaint, Datascope 79. incorporates, as if fully set forth herein, its responses to paragraphs 1 through 78 of the complaint.
- Denies the allegations of paragraph 80 of the complaint, except 80. admits that Rex transferred to Datascope portions of certain of the items listed in Schedule A to the Innermark Transfer Agreement and Schedule A to the Innerlock Transfer Agreement.
- Denies the allegations of paragraph 81 of the complaint, except 81. admits that Rex delivered to Datascope certain of the items listed in Schedule A of the Innermark Transfer Agreement and Schedule A of the Innerlock Transfer Agreement.
 - Denies the allegations of paragraph 82 of the complaint. 82.
 - Denies the allegations of paragraph 83 of the complaint. 83.

- 13 -063982.1001 WP3:1095351.1

FIRST AFFIRMATIVE DEFENSE

Some or all of the causes of action asserted in the complaint fail to state a claim for relief.

SECOND AFFIRMATIVE DEFENSE

Some or all of the causes of action asserted in the complaint are barred by virtue of Rex's material breach of each of the Thrombectomy Transfer Agreement, the Innermark Transfer Agreement and the Innerlock Transfer Agreement (collectively, the "Transfer Agreements"), as more fully described in the counterclaims set forth below.

THIRD AFFIRMATIVE DEFENSE

Some or all of the causes of action asserted in the complaint are barred under the doctrines of waiver, estoppel or laches.

FOURTH AFFIRMATIVE DEFENSE

Rex is barred under the doctrine of unclean hands from receiving some or all of the equitable relief it has requested.

COUNTERCLAIMS

For its counterclaims against counterclaim-defendant Rex, counterclaim plaintiff Datascope alleges on knowledge as to itself and is own acts, and otherwise on information and belief, as follows:

Summary

These counterclaims arise out of Rex's material and continuing 1. breaches of each of the Transfer Agreements. Those agreements required Rex, among other things, to deliver to Datascope various technology and intellectual property, as well as completed and validated product designs (including prototypes) relating to ProLumen, ProLumen Plus and the Innermark and Innerlock sheaths. Under the Transfer Agreements, Rex was required to deliver these items in a timely manner, and in several instances the Transfer Agreements specified a date certain by which Rex was mandated to perform an obligation relating to the transfer of technology, intellectual property or prototypes. However, despite receiving over \$5 million in payments from Datascope under the Transfer Agreements, Rex defaulted in its obligation to make timely delivery of required items to Datascope. Even after being afforded an opportunity to cure its prior breaches, Rex's default has continued unabated. Indeed, to date Rex has never delivered completed, validated ProLumen Plus units or the Innermark or Innerlock sheaths to Datascope.

As a result of Rex's breach of the Transfer Agreements, Datascope 2. has been deprived of the principal benefits it bargained for, in particular delivery of ProLumen Plus and the sheaths. Rex's breach has not only deprived Datascope of the opportunity to realize the profits expected to flow from sales of ProLumen Plus, as well as the Innermark and Innerlock sheaths, but also squandered the efforts of the numerous engineering and marketing executives of Datascope whose labors were focused upon the expected commercialization of these products. Rex is therefore liable for all actual and consequential monetary damages sustained by Datascope. In addition, Rex should be directed forthwith to deliver all "Schedule A" items under the Transfer Agreements that are currently within Rex's possession, custody or control.

Parties and Jurisdiction

Datascope is a corporation organized under the laws of Delaware 3. that maintains offices at 14 Philips Parkway, Montvale, New Jersey.

063982 1001 WP3:1095351.1

- 4. Rex is a limited partnership formed under the laws of Pennsylvania that purports to be in the business of designing, developing and bringing to market medical devices. Rex maintains offices at 555 North Lane, Suite 6101, Conshohocken, Pennsylvania.
- 5. The Court has subject matter jurisdiction over these counterclaims in accordance with, among other things, Rule 13 of the Federal Rules of Civil Procedure.

Factual Allegations

The Thrombectomy Transfer Agreement

- 6. Prior to May 2003, Rex and Datascope discussed products supposedly being developed by Rex and now known as "ProLumen" and "ProLumen Plus." As described by Rex, these products were to be used for the removal of clots (i.e., thrombectomy) in patients undergoing kidney dialysis. Rex indicated that it had already completed development of ProLumen, which it described as a product that would be competitive with, rather than a technological advance over, other devices then on the market for use in the thrombectomy treatment of dialysis patients. Rex described ProLumen Plus as a product still in development that would enhance the capabilities of ProLumen and represent, upon completion, a technological advance over the other devices then available for thrombectomy treatment of dialysis patients.
- 7. In the discussions between the parties, Datascope inquired about the timetable on which Rex could deliver the technology and intellectual property that would permit Datascope to commercialize and sell ProLumen and ProLumen Plus. Such a timetable was relevant to Datascope's efforts to provide an appropriate stream of product offerings to its customers. In addition, the timetable for the introduction of a new medical device is often crucial for success because new product offerings or innovations

- 16 - WP3:1095351.1 063982.1001

by competitors can dampen or even eliminate demand for a particular device. In other words, the later the timetable for the introduction of a new product, the lower the potential for profitable sales.

- Datascope was particularly interested in the timetable for delivery 8. of ProLumen Plus. Since Rex described ProLumen Plus as a significant enhancement in the state of the art for thrombectomy devices, a short timetable for delivery would maximize Datascope's opportunity for profit through commercialization of such a device. In contrast, a longer timetable would jeopardize the competitive advantage of ProLumen Plus.
- In view of these considerations, Rex made several representations 9. and commitments concerning the timetable for the delivery of ProLumen and ProLumen Plus in the Thrombectomy Transfer Agreement, including the following:
 - Rex recited that it had "already developed" ProLumen. (a)
 - Rex transferred to Datascope, effective upon the execution of the (b) agreement, all "technology" relating not only to ProLumen, but also ProLumen Plus. "Technology" was defined as all "knowledge, intellectual property, patents and patent applications, know-how and experience described in detail on Schedule A." Schedule A listed ten items of technology that would embody Rex's work on ProLumen and ProLumen Plus, including the design history file, drawings, testing procedures and data, and technical specifications.

- 17 -063982.1001 WP3:1095351.1

- Rex agreed to a schedule of "milestone payments" under which, (c) following an initial payment of \$1 million upon execution of the Thrombectomy Transfer Agreement, all of Datascope's subsequent payment obligations were conditioned upon the occurrence of a specified event. The last, and largest, milestone payment was for \$2.5 million, and was only to be paid by Datascope within ten days after the "successful conclusion of clinical testing" of ProLumen Plus, and was expressly made "subject to the satisfaction of the conditions listed in Section 8B."
- Rex agreed in Section 8B of the Thrombectomy Transfer (d) Agreement that the final milestone payment by Datascope of \$2.5 million

"shall be made only if, on or before July 1, 2004, Rex both (a) produces (or has produced for it) three qualification lots of Future Transferred Product [ProLumen Plus | each containing 200 units which all successfully meet all of the product's specifications, and (b) obtains FDA approval of the 510(k) for the Future Transferred Product."

Within one year of the date of Thrombectomy Transfer Agreement, 10. Datascope had made three additional milestone payments to Rex relating to ProLumen. Together with the initial \$1 million paid upon execution of the contract, this brought the total payments by Datascope to Rex as of May 2004 under the Thrombectomy Transfer Agreement to at least \$5 million.

063982.1001 WP3:1095351.1

- Although Rex delivered certain of the items called for in Schedule 11. A of the Thrombectomy Transfer Agreement on the ProLumen project, it delivered few of the items called for in Schedule A with respect to ProLumen Plus. For example, Rex has not delivered to Datascope a design history file, a quality plan, complete testing data, certain test fixtures, or various specifications for molds for ProLumen Plus.
- By mid-2004, Datascope had begun manufacturing and marketing 12. ProLumen. However, within months of its introduction, Datascope was forced to initiate a recall of ProLumen because of complaints from some physicians about malfunctions that prevented the device from being turned on, as well as about the durability of a component in the product. The recall resulted from flaws in the design and development work on ProLumen by Rex that were at variance with, and in breach of, the Thrombectomy Transfer Agreement. The recall significantly affected the views of some physicians on the reliability and attractiveness of the product, and thereby impaired Datascope's opportunity to profit from the sale of ProLumen. In order to resolve these complaints about malfunctions and durability, Datascope engineers made adjustments in the design and manufacture of ProLumen.
- As noted above, the Thrombectomy Transfer Agreement required 13. Rex by July 1, 2004 (i) to deliver to Datascope three qualification lots of ProLumen Plus (each containing 200 units) that met all product specifications, and (ii) obtain FDA approval of a 510(k) application on ProLumen Plus. But Rex breached its obligation to do so. Indeed, as noted above, few of the technology items listed in Schedule A with respect to ProLumen Plus were delivered to Datascope by July 1, 2004, much less three

- 19 -063982.1001 WP3:1095351.1

lots of prototypes. Indeed, to date Rex has still not satisfied either of its obligations under paragraph 8B of the Thrombectomy Transfer Agreement.

- Under the Thrombectomy Transfer Agreement, Rex's failure to 14. perform its duties under paragraph 8B relieved Datascope of any obligation to make the milestone payment of \$2.5 million to Rex after July 1, 2004. Rex nonetheless remained obligated to deliver ProLumen Plus, and all related technology or intellectual property, to Datascope. Moreover, it remained in Rex's financial interest to do so, since such delivery could lead to "earn-out" payments by Datascope to Rex of up to 12% of net sales of ProLumen Plus in accordance with Section 3B of the contract.
- By November 2004, Rex had still made little progress in delivery 15. of the technology items called for in Schedule A with respect to ProLumen Plus. As a result, on November 15, 2004, Datascope sent a letter notifying Rex that it was in breach of the Thrombectomy Transfer Agreement because, among other things, of its delay in completing development of ProLumen Plus, as well as Rex's failure to disclose to Datascope design information on a so-called "S" wire relating to ProLumen Plus.
- Despite Datascope's letter, at no time subsequent to November 15, 16. 2004 has Rex cured the breaches described in that communication. In fact, since that date. Rex has not delivered any of the items called for in Schedule A to the Thrombectomy Transfer Agreement with respect to ProLumen Plus that remained undelivered as of November 15, 2004.
- In at least one instance, Rex's failure to deliver information or 17. technology subject to the Thrombectomy Transfer Agreement has been willful. Specifically, Rex has on several occasions claimed that it has developed information and

- 20 -063982.1001 WP3:1095351.1

technology for an advanced component to be used with ProLumen Plus and known as "X-Wire." However, rather than delivering information or technology on the X-Wire to Datascope, Rex has, in violation of the Thrombectomy Transfer Agreement, demanded additional payment from Datascope as a condition of delivering such information and technology.

The Innermark and Innerlock Transfer Agreements

Case 1:05-cv-00028-GMS

- Innermark and Innerlock Transfer Agreements. Under these contracts, Rex recited that it has already developed the Innermark and Innerlock sheaths, and promised to transfer all technology and intellectual property relating to those products, as well to all related sheathing products that Rex was "continuing to develop."
- 19. The Innermark and Innerlock Transfer Agreements reflect the understanding of the parties that, in view of marketing timing sensitivities, Rex would proceed promptly to deliver to Datascope the Innermark and Innerlock products and technologies. Specifically, in paragraph 6B of each contract, Rex represented and warranted that all technical information and assistance called for in the contracts "shall be provided in a timely manner." Similarly, Rex agreed "promptly [to] file all necessary amendments to the 510(k)."
- 20. The Innermark and Innerlock Transfer Agreements provided for an initial payment by Datascope upon signing, followed by two milestone payments that were to be made upon the occurrence of stated conditions. Datascope made the initial payment required upon execution of the contracts, as well as the next milestone payment. Nonetheless, as of November 2004, Datascope had been unable to introduce either the Innermark or Innerlock sheaths to the medical market because, among other things,

- 21 - WP3:1095351.1 063982.1001

- Rex had failed to provide acceptable test data for three (a) qualification lots and a completed digital history file for either product, as required by the contracts.
- Rex had failed to provide specified molds necessary to (b) manufacture the sheaths, as required by the contracts.
- Rex had failed to identify a suitable manufacturer that would (c) produce the sheaths at specified prices, as required by the contracts.
- As a result, the letter sent by Datascope to Rex on November 15, 21. 2004, notified Rex of the foregoing material breaches of the Innermark and Innerlock Transfer Agreements. To date, Rex has failed to remedy any of these breaches. Damages
- Datascope has sustained both monetary and irreparable damage as 22. a result of Rex's multiple breaches of contracts. Such monetary damages include (i) the loss of profits that would have been realized upon the sale of ProLumen Plus and the Innermark and Innerlock sheaths, had those products and related technologies been timely delivered in accordance with Rex's contractual obligations; (ii) the additional cost to, and revenues lost by, Datascope as a result of the recall of ProLumen in mid-2004; and (iii) the cost and lost opportunity associated with Datascope's allocation of additional engineering and marketing resources to the ProLumen, ProLumen Plus, Innermark and Innerlock projects as a result of Rex's multiple breaches of the Transfer Agreements. The irreparable damage to Datascope, for which it has no adequate remedy at law, includes the deprivation of the opportunity to hold, use and exploit multiple patents,

- 22 -063982.1001 WP3:1095351.1

technology and other intellectual property that Rex was obligated, but failed, to deliver to Datascope.

COUNT I [Breach of the Thrombectomy Transfer Agreement]

- 23. Datascope repeats, as if fully set forth, all of the allegations of these counterclaims outside this Count I.
- 24. The Thrombectomy Transfer Agreement is a valid, binding and enforceable contract.
- 25. As more fully described above, Rex breached the Thrombectomy Transfer Agreement by, among other things, each of the following:
 - (a) failing to deliver certain of the items of technology listed on Schedule A with respect to ProLumen;
 - (b) failing to deliver three qualification lots (each with 200 units meeting all specifications) of ProLumen Plus by July 1, 2004, or at any time thereafter;
 - (c) failing to obtain FDA approval of a 510(k) application for ProLumen Plus by July 1, 2004, or any time thereafter;
 - (d) failing at any time to deliver most of the items of technology specified on Schedule A with respect to ProLumen Plus, and
 - (e) failing willfully to transfer to Datascope various items of technology and intellectual property within Rex's possession, custody or control that are related to ProLumen or ProLumen Plus, including the so-called "X-wire," as well as any patents or patent applications pertinent to such items of technology.

- 23 - WP3:1095351.1 063982.1001

- 26. Datascope has sustained both monetary and irreparable damage as a result of the breaches of the Thrombectomy Transfer Agreement, and is entitled to be awarded relief therefore.
- 27. Rex is liable to Datascope for all damages sustained as a result of Rex's breach of the Thrombectomy Transfer Agreement.

COUNT II [Breach of the Innermark Transfer Agreement]

- 28. Datascope repeats, as if fully set forth, all of the allegations of these counterclaims outside this Count II.
- 29. The Innermark Transfer Agreement is a valid, binding and enforceable contract.
- 30. As more fully described above, Rex breached the Innermark Transfer Agreement by, among other things, each of the following:
 - (a) failing to deliver timely, or at any time, three qualification lots (each with 200 units meeting all specifications) of Innermark sheaths; and
 - (b) failing to deliver timely, or at any time, the design history file,molds and certain other items of technology set forth in ScheduleA.
- 31. Datascope has sustained both monetary and irreparable damage as a result of the breach of the Innermark Transfer Agreement, and is entitled to be awarded relief therefore.
- 32. Rex is liable to Datascope for all of the damages sustained as a result of Rex's breach of the Innermark Transfer Agreement.

- 24 - WP3:1095351.1 063982.1001

COUNT III [Breach of the Innerlock Transfer Agreement]

- 33. Datascope repeats, as if fully set forth, all of the allegations of these counterclaims outside this Count III.
- 34. The Innerlock Transfer Agreement is a valid, binding and enforceable contract.
- 35. As more fully described above, Rex breached the Innerlock Transfer Agreement by, among other things, each of the following:
 - (a) failing to deliver timely, or at any time, three qualification lots (each with 200 units meeting all specifications) of Innerlock sheaths; and
 - (b) failing to deliver timely, or at any time, the design history file,molds and certain other technology items set forth in Schedule A.
- 36. Datascope has sustained both monetary and irreparable damage as a result of the breach of the Innerlock Transfer Agreement, and is entitled to be awarded relief therefore.
- 37. Rex is liable to Datascope for all of the damages sustained as a result of Rex's breach of the Innerlock Transfer Agreement.

JURY DEMAND

38. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure,
Datascope Corporation requests a trial by jury on all issues so triable.

WHEREFORE, defendant and counterclaim plaintiff Datascope Corp. respectfully requests that the Court enter judgment as follows:

- 25 - WP3:1095351.1 063982.1001

- (A) dismissing the complaint in its entirety with prejudice;
- (B) awarding all actual, compensatory and consequential damages, in an amount to be determined at trial, in favor of Datascope, and against Rex;
- (C) preliminarily and permanently directing Rex, and any of its general partners or others acting in concert with Rex, to transfer to Datascope all knowledge, know-how, technology, patents and patent applications and other intellectual property (including any such items relating to Schedule A of each of the Transfer Agreements) relating to any and all of ProLumen, ProLumen Plus or the Innermark or Innerlock sheaths;
- (D) preliminarily and permanently enjoining Rex, and any general partners or others acting in concert with it, from conveying or transferring to any person other than Datascope any of the above described knowledge, know-how, technology, patents and patent applications and other intellectual property relating to ProLumen, ProLumen Plus or the Innermark or Innerlock sheaths;
- (E) preliminarily and permanently directing Rex promptly to render to Datascope all assistance reasonably necessary to file, perfect or protect any patents or patent applications relating to the foregoing; and
- (F) awarding such other preliminary and permanent relief as may be just, proper or equitable.

WP3:1095351.1

- 26 -

YOUNG CONAWAY STARGATT & TAYLOR LLP

Rolin P. Bissell (#4434)
Kevin M. Baird (#4219)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19899-0391
(302) 571-6600
kbaird@ycst.com
Attorneys for defendant and
counterclaim-plaintiff Datascope
Corp.

OF COUNSEL:

Robert J. Jossen, Esq. Joseph F. Donley, Esq. Dechert LLP 30 Rockefeller Plaza New York, NY 10112 (212) 698-3500

Dated: March 18, 2005

CERTIFICATE OF SERVICE

I hereby certify that on March 18, 2005, I caused to be electronically filed a true and correct copy of DEFENDANT DATASCOPE CORP.'S ANSWER AND COUNTERCLAIMS with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

Gregory B. Williams, Esquire Fox Rothschild, LLP 919 North Market Street, Suite 1300 P.O. Box 2323 Wilmington, DE 19899-2323

I further certify that on March 18, 2005, I caused a copy of the DEFENDANT DATASCOPE CORP.'S ANSWER AND COUNTERCLAIMS to be served by hand-delivery on the following counsel of record:

Gregory B. Williams, Esquire Fox Rothschild, LLP 919 North Market Street, Suite 1300 P.O. Box 2323 Wilmington, DE 19899-2323

YOUNG CONAWAY STARGATT & TAYLOR, LLP

Kevin M. Baird (No. 4219) The Brandywine Building 1000 West Street, 17th Floor Wilmington, DE 19801

P.O. Box 391 Wilmington, DE 19899-0391 (302) 571-6600 kbaird@ycst.com

Attorneys for Datascope Corp.

WP3.1093649.1 63982.1001